

§ 101.91

21 CFR Ch. I (4–1–14 Edition)

(3) The claim may include information from paragraphs (a) and (b) of this section, which summarize the relationship between diets that include plant sterol/stanol esters and the risk of CHD and the significance of the relationship.

(4) The claim may include information from the following paragraph on the relationship between saturated fat and cholesterol in the diet and the risk of CHD: The scientific evidence establishes that diets high in saturated fat and cholesterol are associated with increased levels of blood total and LDL cholesterol and, thus, with increased risk of CHD. Intakes of saturated fat exceed recommended levels in the diets of many people in the United States. One of the major public health recommendations relative to CHD risk is to consume less than 10 percent of calories from saturated fat and an average of 30 percent or less of total calories from all fat. Recommended daily cholesterol intakes are 300 mg or less per day. Scientific evidence demonstrates that diets low in saturated fat and cholesterol are associated with lower blood total and LDL cholesterol levels.

(5) The claim may state that diets that include plant sterol or stanol esters and are low in saturated fat and cholesterol are consistent with “Nutrition and Your Health: Dietary Guidelines for Americans,” U.S. Department of Agriculture (USDA) and Department of Health and Human Services (DHHS), Government Printing Office (GPO).

(6) The claim may state that individuals with elevated blood total and LDL cholesterol should consult their physicians for medical advice and treatment. If the claim defines high or normal blood total and LDL cholesterol levels, then the claim shall state that individuals with high blood cholesterol should consult their physicians for medical advice and treatment.

(7) The claim may include information on the number of people in the United States who have heart disease. The sources of this information shall be identified, and it shall be current information from the National Center for Health Statistics, the National Institutes of Health, or “Nutrition and Your Health: Dietary Guidelines for Ameri-

cans,” U.S. Department of Agriculture (USDA) and Department of Health and Human Services (DHHS), Government Printing Office (GPO).

(e) *Model health claim.* The following model health claims may be used in food labeling to describe the relationship between diets that include plant sterol or stanol esters and reduced risk of heart disease:

(1) *For plant sterol esters:* (i) Foods containing at least 0.65 g per serving of plant sterol esters, eaten twice a day with meals for a daily total intake of at least 1.3 g, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of the food] supplies _____ grams of vegetable oil sterol esters.

(ii) Diets low in saturated fat and cholesterol that include two servings of foods that provide a daily total of at least 1.3 g of vegetable oil sterol esters in two meals may reduce the risk of heart disease. A serving of [name of the food] supplies _____ grams of vegetable oil sterol esters.

(2) *For plant stanol esters:* (i) Foods containing at least 1.7 g per serving of plant stanol esters, eaten twice a day with meals for a total daily intake of at least 3.4 g, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. A serving of [name of the food] supplies _____ grams of plant stanol esters.

(ii) Diets low in saturated fat and cholesterol that include two servings of foods that provide a daily total of at least 3.4 g of vegetable oil stanol esters in two meals may reduce the risk of heart disease. A serving of [name of the food] supplies _____ grams of vegetable oil stanol esters.

[65 FR 54717, Sept. 8, 2000; 65 FR 70466, Nov. 24, 2000, as amended at 66 FR 66742, Dec. 27, 2001; 68 FR 15355, Mar. 31, 2003; 70 FR 41958, July 21, 2005]

Subpart F—Specific Requirements for Descriptive Claims That Are Neither Nutrient Content Claims nor Health Claims

§ 101.91 Gluten-free labeling of food.

(a) *Definitions.* (1) The term “gluten-containing grain” means any one of

the following grains or their crossbred hybrids (e.g., triticale, which is a cross between wheat and rye):

- (i) Wheat, including any species belonging to the genus *Triticum*;
- (ii) Rye, including any species belonging to the genus *Secale*; or
- (iii) Barley, including any species belonging to the genus *Hordeum*.

(2) The term “gluten” means the proteins that naturally occur in a gluten-containing grain and that may cause adverse health effects in persons with celiac disease (e.g., prolamins and glutelins).

(3) The labeling claim “gluten-free” means:

(i) That the food bearing the claim in its labeling:

(A) Does not contain any one of the following:

(1) An ingredient that is a gluten-containing grain (e.g., spelt wheat);

(2) An ingredient that is derived from a gluten-containing grain and that has not been processed to remove gluten (e.g., wheat flour); or

(3) An ingredient that is derived from a gluten-containing grain and that has been processed to remove gluten (e.g., wheat starch), if the use of that ingredient results in the presence of 20 parts per million (ppm) or more gluten in the food (i.e., 20 milligrams (mg) or more gluten per kilogram (kg) of food); or

(B) Inherently does not contain gluten; and

(ii) Any unavoidable presence of gluten in the food bearing the claim in its labeling is below 20 ppm gluten (i.e., below 20 mg gluten per kg of food).

(b) *Requirements.* (1) A food that bears the claim “gluten-free” in its labeling and fails to meet the requirements of paragraph (a)(3) of this section will be deemed misbranded.

(2) A food that bears the claim “no gluten,” “free of gluten,” or “without gluten” in its labeling and fails to meet the requirements of paragraph (a)(3) of this section will be deemed misbranded.

(3) A food that bears the term “wheat” in the ingredient list or in a separate “Contains wheat” statement in its labeling, as required by 21 U.S.C. 343(w)(1)(A), and also bears the claim “gluten-free” or a claim identified in paragraph (b)(2) of this section will be

deemed misbranded unless the word “wheat” in the ingredient list or in the “Contains wheat” statement is followed immediately by an asterisk (or other symbol) that refers to another asterisk (or other symbol) in close proximity to the ingredient statement that immediately precedes the following: “The wheat has been processed to allow this food to meet the Food and Drug Administration (FDA) requirements for gluten-free foods.”

(c) *Compliance.* When compliance with paragraph (b) of this section is based on an analysis of the food, FDA will use a scientifically valid method that can reliably detect the presence of 20 ppm gluten in a variety of food matrices, including both raw and cooked or baked products.

(d) *Preemption.* A State or political subdivision of a State may not establish or continue into effect any law, rule, regulation, or other requirement that is different from the requirements in this section for the definition and use of the claim “gluten-free,” as well as the claims “no gluten,” “free of gluten,” or “without gluten.”

[78 FR 47178, Aug. 5, 2013]

§ 101.93 Certain types of statements for dietary supplements.

(a)(1) No later than 30 days after the first marketing of a dietary supplement that bears one of the statements listed in section 403(r)(6) or the Federal Food, Drug, and Cosmetic Act, the manufacturer, packer, or distributor of the dietary supplement shall notify the Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, that it has included such a statement on the label or in the labeling of its product. An original and two copies of this notification shall be submitted.

(2) The notification shall include the following:

(i) The name and address of the manufacturer, packer, or distributor of the dietary supplement that bears the statement;

(ii) The text of the statement that is being made;